August 9, 2019

Avenu Medical, Inc.
Dave Campbell
VP of Quality Assurance and Regulatory Affairs
27123 Calle Arroyo, Suite 2101
San Juan Capistrano, CA 92675

Re: K191114
Trade/Device Name: Ellipsys Vascular Access System (Ellipsys System), (Power Controller Model No. AMI-1001, Catheter Model No. AMI-6005, and Crossing Needle Model No. AMI-3000)
Regulation Number: 21 CFR 870.1252
Regulation Name: Percutaneous Catheter for Creation of an Arteriovenous Fistula for Hemodialysis Access
Regulatory Class: Class II
Product Code: PQK
Dated: July 10, 2019
Received: July 12, 2019

Dear Mr. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brian Pullin
Assistant Director
DHT2B: Division of Circulatory Support, Structural and Vascular Prostheses
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191114

Device Name
Ellipsys® Vascular Access System (Ellipsys® System)
(Power Controller, Model No. AMI-1001; Catheter, Model No. AMI-6005 & Needle, Model No. AMI-3000)

Indications for Use *(Describe)*
The Ellipsys® System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Avenu Medical, Inc.
27123 Calle Arroyo, Suite 2101
San Juan Capistrano, CA 92675

Phone: 949-276-2483
FAX: 949-276-2493

Contact Person: Dave Campbell
Date Prepared: April 25, 2019

II. DEVICE

Name of Device: Ellipsys Vascular Access System (Ellipsys® System), Model AMI-1001, Model AMI-6005 and AMI-3000

Common or Usual Name: Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access

Regulatory Class: II

Product Code: PQK

Regulation Number: 21 CFR 870.1252

III. PREDICATE DEVICE

Ellipsys Vascular Access System (Ellipsys® System), Model AMI-1001, Model AMI-6005 and AMI-3000

510(k) Premarket Notification: K183615

Regulation Number: 21 CFR 870.1252

This predicate has not been subject to a recall.

IV. DEVICE DESCRIPTION

The device that is the subject of this 510(k) is a modified Ellipsys Vascular Access System. The Ellipsys System gained market clearance through the 510(k) Premarket Notification pathway (K183615). The specific modification subject to this submission consists of an update to the Instructions for Use to allow an additional procedural step for balloon dilation of the anastomosis junction at the radial artery and adjacent outflow vein of the AVF immediately after creation with the Ellipsys Catheter.

The Ellipsys System remains a catheter-based system that is used to percutaneously create a vascular anastomosis of the proximal radial artery and adjacent perforating vein using direct current (DC) thermal heating. No changes have been made to the intended use, technological

characteristics, design, function, or manufacturing processes of the Ellipsys Power Controller (AMI-1001), Ellipsys Needle (AMI-3000) or the Ellipsys Catheter (AMI-6005).

V. INDICATIONS FOR USE

The Ellipsys® System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis. No changes have been made to the indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ellipsys Vascular Access System described and cleared by FDA in 510(k) K183615, serves as the predicate for the modified device that is the subject of this 510(k). Both the modified device and the predicate device are identical in design and intended use. The technological principle for both the modified Ellipsys System and the predicate device is endovascular creation of an AV fistula. Both systems utilize ultrasonically guided endovascular techniques and instrumentation for approximating (bringing together) the arterial and venous vessel walls and applying DC thermal energy to join the target vessels creating a side by side anastomosis and thereby creating an AV fistula for dialysis access.

The only change in the modified device is an added procedural step of balloon dilation immediately post-AVF creation, though all other characteristics remain unchanged. The purpose of the balloon dilation step is to mitigate the acute vessel spasm and partial occlusion commonly seen at the anastomosis and outflow vein associated with any AVF creation (e.g. surgical or Ellipsys). As the dilation is performed immediately post-AVF creation, the same initial access puncture, guidewire and sheath can be utilized, saving additional potential risks related to placement of these devices during the index procedure.

The modified and predicate devices are based on the same technological elements as described below:

Power Controller, Model #AMI-1001

- Software controlled device that guides the user through the procedure using visual prompts via a graphical user interface, monitors the closure of the catheter tip, and supplies controlled DC energy to the catheter's heating element.

Ellipsys Needle, Model #AMI-3000

- The Needle is inserted into the vasculature over a guidewire through an introducer sheath to cross from the vein into the adjacent artery.

Ellipsys Catheter, Model #AMI-6005

- The Catheter is inserted over the guidewire through the introducer sheath so the distal tip is inside the artery and the proximal portion of the tip remains in the vein. The

catheter mechanically captures and approximates the vessel walls.

- The Catheter seals the walls of the proximal radial artery and the adjacent vein creating an arteriovenous fistula utilizing DC thermal energy delivered by the Power Controller.

The following provides a technological comparison between the modified and predicate devices:

The Ellipsys Power Controller (AMI-1001) remains unchanged from the predicate. No changes have been made to the hardware design, software design, power source, control algorithm, thermal profile or manufacturing processes.

The Ellipsys the Needle (AMI-3000) is identical to the predicate. There are no changes to the design, patient contact materials, manufacturing processes, packaging materials or function of the modified device.

The Ellipsys Catheter (AMI-6005) is identical to the predicate. There are no changes to the design, patient contact materials, manufacturing processes, packaging materials or function of the modified device.

The Instructions for Use (IFUs) for the catheter will change to reflect the added procedural step.

A comparison of the technological characteristics of the modified Ellipsys System versus the predicate is provided in **TABLE 6.1** below.

TABLE 6.1 - Device Comparison

Characteristic	**Modified Device (AMI-1001/AMI-6005/AMI-3000)**	**Modified Device (AMI-1001/AMI-6005/AMI-3000)**	**Comparison**
Indication for Use	No change	No change	Identical
Instructions for Use (IFU)	No change	Clarify use of post-AVF balloon dilation	Similar
Power Controller (AMI-1001)			
Design: Hardware/Electronics	No change	Existing	Identical
Energy Source & Type	No change	Mechanical DC thermal energy	Identical
System Software	No change	System software (C^{++} code)	Identical
Temperature Control Algorithm	No change	PID control	Identical
Temperature Profile	No change	Maximum of 7 cycles (2 sec @ 700°F followed by 8 sec cooling phase)	Identical
Catheter Compatibility	No change	AMI-6005	Identical
Needle (AMI-3000)			

Design	No change	Existing	Identical
Materials - Patient	No change	ABS/Stainless Steel (SS)	Identical
Packaging Configuration	No change	Needle individually packaged in a separate Tyvek pouch w/ backer card	Identical
Catheter (AMI-6005)			
Function & Operation	No change	Function: Approximates (brings together) the target arterial and venous vessel walls and applies thermal energy to create an anastomosis. Operation: Catheter Handle & Thumb Tab control insertion and Actuation of the tip.	Identical
Materials - Patient Contact	No change	ABS/Polyimide/Parylene/Stainless Steel (SS)	Identical
Catheter Design	No change	Existing	Identical
Packaging Configuration	No change	Catheter individually packaged in a separate Tyvek Pouch w/ backer card	Identical

There are no technological differences between the modified Ellipsys System and the predicate device and as a result no new or different questions of safety and effectiveness are raised. Performance data described in Section VII in support of the modification to the instructions for use establishes that the device is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

The following performance data are provided in support of the special controls requirements of 21 CFR 870.1252 and the substantial equivalence determination. All devices used for evaluation of performance were representative of finished devices.

1) Clinical Performance Testing

Clinical data is provided in support of the special controls requirement and substantial equivalence for the modification of the Instructions for Use of the Ellipsys System. The data provided is a post-market summary of data from two different physician sources in the United States (US) and outside the United States (OUS) to support continued safety, efficacy and substantial equivalence. This data and has been summarized, analyzed, and is being submitted in support of this added procedural step of balloon dilatation after AVF creation. The additional procedural step as described in the modified Instructions for Use results in the creation of the AVF in the same anatomic location in the proximal radial artery.

2) Summary of Clinical Performance Testing

Clinical Data Design

Both the US and OUS studies were prospective, IRB approved registry studies. End stage renal disease (ESRD) patients were screened for eligibility for a proximal radial artery to

perforating vein arteriovenous fistula (AVF) per Ellipsys commercial Instructions For Use (IFUs). All patients who were determined to be eligible and provided informed consent (IC) had their procedures scheduled. All patients had their AVF created per Ellipsys commercial IFUs. All patients had immediate post-AVF creation balloon dilation per proposed IFUs. All patients were brought back for follow-up monitoring visits per clinical standard of care. In the US study, patients were followed at 1 week, 4 weeks, and 3 months. In the OUS study, patients completed follow-up visits between days 30-60 and after at least 90 days. Data were summarized and reported for various parameters including: technical success, clinical success, maturation procedures, maintenance procedures, procedural success for secondary procedures, suitability for dialysis, procedural clinical complications, and AVF patency as determined by ultrasound and/or physical examination. Data were collected on case report forms and were reported by the study investigators.

Clinical Results

In the US study, a total of 11 adverse events (AEs) were reported among the 55 subjects (11/55 = 20%) throughout 90 days. The complications included 9 access thrombosis-stenosis events and 2 mild hematomas at the access site.

In the OUS study, a total of 16 AEs were reported among the 200 subjects (16/200 = 8%). The AEs included 9 deaths (9/200 = 4.5%), 6 access thromboses, and 1 pseudoaneurysm.

The rates of AEs appeared to be numerically similar to the rates of AEs observed in the IDE study that supported the De Novo application for this device (DEN170004). Given that the mean duration of patient follow-up in the OUS study was 352 days (almost 12 months), the death rate of 4.5% appears to be substantially equivalent to the 12-month death rate from the De Novo study (7.8%). The reported rate of acute occlusions of the AVF was 1/255 (0.4%), which appeared to be numerically lower than the rate of acute occlusions of the AVF in the De Novo IDE study, where 15/103 subjects (14.6%) experienced an occlusion of the AVF within 24 hours of the study procedure. There were no new adverse event types experienced as a result of implementation of the balloon dilation procedure in either study.

The number of secondary procedures required to achieve maturation and/or maintenance of the Ellipsys AVF appeared to be numerically lower than in the De Novo IDE study. The reported follow-up data appeared to show that AVF patency and the rates of anastomotic complications were substantially equivalent to the predicate, although the data were not adjudicated or reviewed by independent third parties. Long-term data regarding AVF complications, adverse events, AVF patency, and AVF functionality will be collected in a post market evaluation.

VIII. CONCLUSIONS

Based on a comparison of the additional data related to the modification to the Instructions for Use, it has been established that the modified Ellipsys System is substantially equivalent to the legally marketed predicate device. The modification of the Instructions for Use that provides for an additional procedural step of balloon dilatation immediately following AVF

creation with the Ellipsys Catheter did not raise new or different questions of safety and effectiveness. Additionally, the data and information in the 510(k) demonstrate that the modified device is substantially equivalent to the predicate device.